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(54) [Title of the Invention] Device for diagnosing abnormalities in body fluids

(57) [Abstract]
[Issue] To enable more accurate measurements of abnormalities in extracellular fluids, such as oedema.

[Means of Resolution] A signal output circuit 5 feeds a multi-frequency probe current Ia to a subject's body. A current detection circuit 6 detects the probe current Ia flowing through the subject's body for each frequency. A voltage detection circuit 7 detects the voltage Vp between the subject's hands and feet for each frequency. A CPU 10 measures the bioelectrical impedance on the basis of the current Ia and voltage Vp which have been detected, and calculates the fluid volume ratio between the intracellular fluid and extracellular fluid in the subject's body on the basis of the measured bioelectrical impedance. The absence or presence of oedema is then determined by comparing the calculated fluid volume ratio with the standard fluid volume ratio which is preset and recorded (the fluid volume ratio between the intracellular fluid and extracellular fluid in a healthy subject in a normal state), and the determination results are then displayed on a screen with an added message indicating that "the subject is suffering from oedema" or "the body fluids of the subject are in a normal state".

8a start/end switch
8b mode setting switch
9 display device
5 signal output circuit
52 measurement signal generator
53 output buffer
6 current detection circuit
64 sampling memory
63 A/D converter
61 I/V converter

7 voltage detection circuit

74 sampling memory

73 A/D converter

71 differential amplifier

4A device for diagnosing abnormalities in body fluids

[Scope of the Patent Claims]

[Claim 1] Device for diagnosing abnormalities in body fluids, characterized in that it is provided with:

bioelectrical impedance measurement means for measuring the bioelectrical impedance in a subject's body by generating a multi-frequency probe current which is then fed into the subject's body for each frequency;

resistance value calculation means for calculating the intracellular fluid resistance and extracellular fluid resistance in the subject's body, or the value of a parameter relating to the resistance, on the basis of the bioelectrical impedance in the subject's body measured by the bioelectrical impedance measurement means;

fluid volume ratio calculation means for calculating the fluid volume ratio between the intracellular fluid and extracellular fluid in the subject's body on the basis of the intracellular fluid resistance and extracellular fluid resistance, or the abovementioned parameter value, as calculated by the resistance value calculation means;

memory means for pre-storing, as the standard fluid volume ratio, an upper limit value and a lower limit value for the fluid volume ratio between the intracellular fluid and the extracellular fluid in a healthy subject in a normal state;

body fluid abnormality determination means for determining whether or not a subject is suffering from an abnormality in body fluids by comparing the fluid volume ratio in the subject's body calculated by the fluid volume ratio calculation means, and the standard fluid volume ratio read out from the memory means; and

display control means for displaying the results of the determination performed by the body fluid abnormality determination means on a display device.

[Claim 2] Device for diagnosing abnormalities in body fluids according to Claim 1, characterized in that the bioelectrical impedance measurement means measure the bioelectrical impedance or bioelectrical admittance in the subject's body for each frequency in the probe current which is fed into the subject's body, obtain the impedance locus or admittance locus using the least squares method for the calculation, in accordance with the measured bioelectrical impedance or bioelectrical admittance for each frequency, and calculate the bioelectrical impedance or bioelectrical admittance in the subject's body at a frequency of 0 and at an infinite frequency from the impedance locus or admittance locus obtained; and
the resistance value calculation means calculate the intracellular fluid resistance and extracellular fluid resistance in the subject's body, or the value of a parameter relating to the resistance, on the basis of the bioelectrical impedance or bioelectrical admittance in the subject's body at a frequency of 0 and at an infinite frequency which are calculated by the bioelectrical impedance measurement means.

[Claim 3] Device for diagnosing abnormalities in body fluids according to Claim 1 or 2, characterized in that it further comprises body characteristics data input means for inputting at least one selected from the subject's height, weight, age and sex as body characteristics data; and
the fluid volume ratio calculation means calculate the fluid volume ratio in the subject's body on the basis of the intracellular fluid resistance and extracellular fluid resistance, or the abovementioned parameter value, as calculated by the resistance value calculation means,

and the body characteristics data of the subject which is input from the body characteristics data input means.

[Claim 4] Device for diagnosing abnormalities in body fluids according to Claim 1, 2 or 3, characterized in that it further comprises body characteristics data input means for inputting at least one selected from the subject’s height, weight, age and sex as body characteristics data; and

the memory means pre-stores, as the standard fluid volume ratio, the upper limit value and lower limit value of the fluid volume ratio in a healthy subject in a normal state, for each body characteristics category including at least one selected from height range, weight range, age range and sex, in correspondence to the input body characteristics data of the subject; and

the body fluid abnormality determination means determine whether or not a subject is suffering from an abnormality in body fluids by comparing the fluid volume ratio in the subject’s body calculated by the fluid volume ratio calculation means, and the desired standard fluid volume ratio which is selectively read out from the memory means on the basis of the body characteristics data input from the body characteristics data input means.

[Claim 5] Device for diagnosing abnormalities in body fluids according to Claim 1, 2, 3 or 4, characterized in that the body fluid abnormality determination means determine whether or not a subject is suffering from oedema or dehydration by comparing the fluid volume ratio in the subject’s body calculated by the fluid volume ratio calculation means, and the standard fluid volume ratio read out from the memory means; and

the display control means provide a display on a display device indicating that: “the subject is suffering from oedema or dehydration” or “the body fluids of the subject are in a normal state”, according

to the results of the determination performed by the body fluid abnormality determination means.

[Detailed Description of the Invention]

[0001]

[Technical Field of the Invention] The present invention relates to a device for diagnosing abnormalities in body fluids which makes it possible to electrically measure abnormalities in body fluids (especially abnormalities in extracellular fluids), and more specifically the present invention relates to a device for diagnosing abnormalities in body fluids which is suitable for use in diagnosing oedema or dehydration etc.

[0002]

[Prior Art] Oedema and dehydration etc. are conditions which occur when there is an unusually high volume or an unusually small volume of body fluid, especially extracellular fluid, but conventional methods of determining whether or not a subject is suffering from an abnormality in body fluids depend largely on a subjective assessment carried out by external observation of the face and hands/feet, or measurement of body weight. However, mistakes can be easily made in this case. In this regard, a technique known as bioelectrical impedance has been proposed as a way of making an objective assessment of abnormalities in body fluids, this being a technique which involves obtaining the intracellular fluid resistance and the extracellular fluid resistance in the subject's body, and measuring the respective volumes of intracellular fluid and extracellular fluid and the water content of the body in accordance with the intracellular fluid resistance and the extracellular fluid resistance which were obtained (see "Bioelectrical impedance as a means of evaluating body composition", Baumgartner, R.N., et al.; "Bioelectrical impedance and clinical applications thereof", Japanese Journal of Medical Electronics and

Biological Engineering, Yutaka KANAI, 20(3), Jun. 1982; "Estimation of water distribution using impedance and clinical applications thereof", Japanese Journal of Medical Electronics and Biological Engineering, Makoto HAENO, et al., 23(6), 1985, etc.). In bioelectrical impedance, four surface electrodes are attached to specific regions on the skin of a subject, for example two on the back of a hand, and two on top of the foot on the same side of the body as the abovementioned hand, and a minute sine wave AC is made to pass between two electrodes between the back of the hand and the top of the foot; the minute current is swept in a frequency range of 3 - 400 kHz, and the voltage between the hand and foot is detected from the remaining two electrodes, whereby the low-frequency and high-frequency bioelectrical impedance is measured. The intracellular fluid resistance and extracellular fluid resistance are then obtained on the basis of the measured low-frequency and high-frequency bioelectrical impedance, the respective volumes of intracellular fluid and extracellular fluid are then estimated from the intracellular fluid resistance and extracellular fluid resistance which were obtained, and these volumes are summed in order to estimate the water content of the body.

[0003] A brief description will be given next of the principle behind bioelectrical impedance. In the body, electricity is chiefly carried by ions in intracellular and extracellular electrolyte solutions, and the total amount of conductivity in the body is roughly equal to the total amount of conductivity in the water contained in the body. Furthermore, as shown in Figure 9, the cells 1, 1, ... which make up body tissue are surrounded by cell membranes 2, 2, ..., and these cell membranes 2, 2, ... can be seen, electrically speaking, as high-capacity (reactance) capacitors. This means that the bioelectrical impedance can be considered as the parallel combined impedance consisting of the

extracellular fluid impedance comprising only the extracellular fluid resistor Re and the intracellular fluid impedance comprising a series connection between the intracellular fluid resistor Ri and the cell membrane capacitor Cm, as shown in Figure 10(a). In a human body represented by this kind of electrical equivalent circuit, the current applied from the outside is such that when the frequency is very low, the electrical impedance (capacitance Cm) of the cell membranes 2, 2, ... is too high to allow current to pass, and therefore current only flows through the extracellular fluid 3, as shown by the solid lines A, A, ... in Figure 9. This means that the bioelectrical impedance which is measured only represents the extracellular fluid resistor Re on its own. However, as the frequency becomes higher, the current which can flow through the cell membranes 2, 2, ... increases, and the bioelectrical impedance which is measured at this point contains a resistance component and a reactance component. When the frequency is very high, the current passes right through the inside of the cells 1, 1, ..., as shown by the broken lines B, B, ... in Figure 9, and the cell membranes 2, 2, ... lose capacitive performance, which means that once again it is only the combined resistance $Ri \cdot Re/(Ri+Re)$ which is measured.

[0004] In this way, the bioelectrical impedance when the frequency is very high or very low contains only a resistance component, and therefore it is possible to obtain the extracellular fluid resistance Re and intracellular resistance Ri separately by measuring the low-frequency (preferably frequency at 0) impedance and the high-frequency (preferably infinite frequency) impedance. The extracellular fluid resistance Re and intracellular resistance Ri obtained in this way are specific to each individual subject, and can be considered to reflect the body water distribution (the volumes of extracellular fluid and intracellular fluid)

of each subject. Bioelectrical impedance is a measurement method which utilizes these properties in order to estimate the volumes of extracellular fluid and intracellular fluid.

[0005] It should be noted that actual body tissues comprise cells having various irregular sizes, and therefore the electrical equivalent circuit is not the simple circuit shown in Figure 10(a), rather it is represented by the distribution time constant circuit shown in Figure 10(b) in which the time constant τ = Cmk Rik (where Rik is the intracellular fluid resistance of each cell and Cmk is the cell membrane capacitance of each cell) is distributed, and this represents the basic principle.

[0006]

[Issues to be Resolved by the Invention] To be precise, abnormalities in body fluids, such as oedema and dehydration, are determined to be present when the balance between extracellular fluid and intracellular fluid breaks down, and there is too much or too little of one or the other, but the conventional body fluid measurement method described above only focuses on the volume of extracellular fluid, and does not make it possible to determine abnormalities in body fluid such as oedema and dehydration etc., and therefore it is lacking in accuracy.

[0007] The present invention has been devised in view of the situation outlined above, and it aims to provide a device for diagnosing abnormalities in body fluids which makes it possible to measure abnormalities in body fluids simply and with greater accuracy.

[0008]

[Means of Resolving the Issues] In order to resolve the issues mentioned above, the device for diagnosing abnormalities in body fluids according to the invention

disclosed in Claim 1 is characterized in that it is provided with: bioelectrical impedance measurement means for measuring the bioelectrical impedance in a subject’s body by generating a multi-frequency probe current which is then fed into the subject’s body for each frequency; resistance value calculation means for calculating the intracellular fluid resistance and extracellular fluid resistance in the subject’s body, or the value of a parameter relating to the resistance, on the basis of the bioelectrical impedance in the subject’s body measured by the bioelectrical impedance measurement means; fluid volume ratio calculation means for calculating the fluid volume ratio between the intracellular fluid and extracellular fluid in the subject’s body on the basis of the intracellular fluid resistance and extracellular fluid resistance, or the abovementioned parameter value, as calculated by the resistance value calculation means; memory means for pre-storing, as the standard fluid volume ratio, an upper limit value and a lower limit value for the fluid volume ratio between the intracellular fluid and the extracellular fluid in a healthy subject in a normal state; body fluid abnormality determination means for determining whether or not a subject is suffering from oedema by comparing the fluid volume ratio in the subject’s body calculated by the fluid volume ratio calculation means, and the standard fluid volume ratio read out from the memory means; and display control means for displaying the results of the determination performed by the body fluid abnormality determination means on a display device.

[0009] Furthermore, the invention disclosed in Claim 2 relates to the device for diagnosing abnormalities in body fluids disclosed in Claim 1 and is characterized in that the bioelectrical impedance measurement means measure the bioelectrical impedance or bioelectrical admittance in the subject’s body for each frequency in the probe current which is fed into the subject’s body,

obtain the impedance locus or admittance locus using the least squares method for the calculation, in accordance with the measured bioelectrical impedance or bioelectrical admittance for each frequency, and calculate the bioelectrical impedance or bioelectrical admittance in the subject’s body at a frequency of 0 and at an infinite frequency from the impedance locus or admittance locus obtained; and the resistance value calculation means calculate the intracellular fluid resistance and extracellular fluid resistance in the subject’s body, or the value of a parameter relating to the resistance, on the basis of the bioelectrical impedance or bioelectrical admittance in the subject’s body at a frequency of 0 and at an infinite frequency which are calculated by the bioelectrical impedance measurement means.

[0010] Furthermore, the invention disclosed in Claim 3 relates to the device for diagnosing abnormalities in body fluids disclosed in Claim 1 or 2 and is characterized in that it further comprises body characteristics data input means for inputting at least one selected from the subject’s height, weight, age and sex as body characteristics data; and the fluid volume ratio calculation means calculate the fluid volume ratio in the subject’s body on the basis of the intracellular fluid resistance and extracellular fluid resistance, or the abovementioned parameter value, as calculated by the resistance value calculation means, and the body characteristics data of the subject which is input from the body characteristics data input means.

[0011] Furthermore, the invention disclosed in Claim 4 relates to the device for diagnosing abnormalities in body fluids disclosed in Claim 1, 2 or 3 and is characterized in that it further comprises body characteristics data input means for inputting at least one selected from the subject’s height, weight, age and sex as body characteristics data; and the memory means

pre-stores, as the standard fluid volume ratio, the upper limit value and lower limit value of the fluid volume ratio in a healthy subject in a normal state, for each body characteristics category including at least one selected from height range, weight range, age range and sex, in correspondence to the input body characteristics data of the subject; and the body fluid abnormality determination means determine whether or not a subject is suffering from an abnormality in body fluids by comparing the fluid volume ratio in the subject's body calculated by the fluid volume ratio calculation means, and the desired standard fluid volume ratio which is selectively read out from the memory means on the basis of the body characteristics data input from the body characteristics data input means.

[0012] Furthermore, the invention disclosed in Claim 5 relates to the device for diagnosing abnormalities in body fluids disclosed in Claim 1, 2, 3 or 4 and is characterized in that the body fluid abnormality determination means determine whether or not a subject is suffering from oedema or dehydration by comparing the fluid volume ratio in the subject's body calculated by the fluid volume ratio calculation means, and the standard fluid volume ratio read out from the memory means; and the display control means display on a display device: "the subject is suffering from oedema or dehydration" or "the body fluids of the subject are in a normal state", according to the results of the determination performed by the body fluid abnormality determination means.

[0013]

[Action] In the configuration of the present invention, the bioelectrical impedance measurement means measure the bioelectrical impedance in a subject's body by generating a multi-frequency probe current which is then fed into the subject's body for each frequency.

The resistance value calculation means calculate the intracellular fluid resistance and extracellular fluid resistance in the subject’s body, or the value of a parameter relating to the resistance, on the basis of the bioelectrical impedance in the subject’s body measured by the bioelectrical impedance measurement means. The fluid volume ratio calculation means calculate the fluid volume ratio between the intracellular fluid and extracellular fluid in the subject’s body on the basis of the intracellular fluid resistance and extracellular fluid resistance, or the abovementioned parameter value, as calculated by the resistance value calculation means. The memory means pre-store, as the standard fluid volume ratio, an upper limit value and a lower limit value for the fluid volume ratio between the intracellular fluid and the extracellular fluid in a healthy subject in a normal state. The body fluid abnormality determination means determine whether or not a subject is suffering from an abnormality in body fluids by comparing the fluid volume ratio in the subject’s body calculated by the fluid volume ratio calculation means, and the standard fluid volume ratio read out from the memory means. The display control means display the results of the determination performed by the body fluid abnormality determination means on a display device.

[0014] The relationship in the balance between extracellular fluid and intracellular fluid (the proportions thereof) is(are) taken into account in determining abnormalities in body fluids using the configuration of the present invention, and therefore the result is consistent with the actual situation, and the reliability can be improved. Furthermore, a computer is used as an automatic diagnostic device, and therefore determination results can be quickly obtained through a simple operation. In addition, the display device provides a display indicating that: “the subject is suffering from oedema or dehydration” or “the body

fluids of the subject are in a normal state", and therefore it is very user-friendly. The invention can therefore be used as healthcare equipment to aid diagnosis in welfare institutions or in domestic settings, among others.

[0015] Furthermore, in the configuration of the present invention, the impedance locus or admittance locus is obtained using the least squares method for the calculation, in accordance with the measured bioelectrical impedance or bioelectrical admittance for each frequency, and the bioelectrical impedance at a frequency of 0 and at an infinite frequency is calculated from the loci obtained, and therefore it is possible to avoid the effects of stray capacitance or exogenous noise in the high-frequency feed, and it is also possible to avoid direct feeding of direct current into the body. The bioelectrical impedance can therefore be measured more accurately.

[0016]

[Mode of Embodiment of the Invention] A mode of embodiment of the present invention will be described below with reference to the figures. The invention will be described in specific terms with the aid of exemplary embodiments.

◊ First Exemplary Embodiment

Figure 1 is a block diagram showing the electrical configuration of the device for diagnosing abnormalities in body fluids according to the first exemplary embodiment of the present invention; Figure 2 is a schematic showing the diagnostic device in use; Figure 3 illustrates the operation of the diagnostic device, and specifically it shows the impedance locus in the body; Figure 4 is a flowchart showing the processing procedure for operation of the diagnostic device; and Figures 5 and 6 show an example of the display which is part of the diagnostic device. The

device 4A for diagnosing abnormalities in body fluids according to this example performs a diagnosis for abnormalities in water distribution in a subject's body using bioelectrical impedance, and displays the results of the diagnosis; as shown in Figures 1 and 2, the basic structure of the device consists of: a signal output circuit 5 for feeding a multi-frequency probe current Ib into the body of a subject M; a current detection circuit 6 for detecting the probe current Ib flowing between the hands and feet of the subject M; a voltage detection circuit 7 for detecting the voltage Vp between the hands and feet of the subject M at the same detection timing as the current detection circuit 6; a start/end switch 8a whereby the operator (or subject) instructs the start of measurement/end of measurement; a mode setting switch 8b whereby the operator (or subject) selects oedema selection mode or dehydration selection mode; a display device 9 for displaying the diagnosis results; a CPU (central processing unit) 10 for performing various controls/calculations; a ROM 11 for storing the processing programs of the CPU 10; a RAM 12 in which a data region for temporarily storing various kinds of data and the operating region of the CPU 10 are set; and four surface electrodes Hp, Hc, Lp, Lc which are conductively attached to the surface of the skin on the back of the hand H and the top of the foot L of the subject M when measurements are taken.

[0017] Here, the surface electrodes Hc, Hp are attached to the back of the right hand H of the subject M, and the surface electrodes Lp, Lc are attached to the top of the right foot L of the subject M with a conductive cream in between. The two surface electrodes Hc, Lc serve to feed the probe current Ib into the body of the subject M while also detecting the probe current Ib flowing between the right hand and foot of the subject M, and the two surface electrodes Hp, Lp serve to

detect the voltage Vp produced between the right hand and foot of the subject M.

[0018] The signal output circuit 5 comprises a PIO (parallel interface) 51, a measurement signal generator 52 and an output buffer 53. The measurement signal generator 52 repeatedly generates a measurement signal (current) Ia which is scanned over the range of 1 kHz – 400 kHz at intervals of 15 kHz, for example, in line with instructions from the CPU 10 which are carried via the PIO 51, throughout the whole measurement period and at a prescribed measurement period, and the signal is input to the output buffer 53. The output buffer 53 sends the input measurement signal Ia to the surface electrode Hc as the multi-frequency probe current Ib while maintaining the signal at a constant current.

[0019] The basic structure of the current detection circuit 6 consists of: an I/V converter (current/voltage converter) 61, a bandpass filter (BPF) 62, an A/D converter (analogue/digital converter) 63 and a sampling memory (ring buffer) 64. The I/V converter 61 detects the probe current Ib flowing between the two surface electrodes Hc, Lc which are attached to the back of the hand H and the top of the foot L of the subject M, and converts this current to a voltage signal Vb, after which the converted voltage signal Vb is supplied to the bandpass filter 62. The bandpass filter 62 only allows the passage of the voltage signal component in the region of 1 kHz – 800 kHz from the voltage signal Vb which has been input, and this is then supplied to the A/D converter 63. The A/D converter 63 converts the analogue voltage signal Vb which has been input to a digital voltage signal Vb in accordance with a digital conversion instruction issued by the CPU 10, after which the digitized voltage signal Vb is stored in the sampling memory 64 as current data Vb for each sampling period and each frequency of the measurement signal Ia. Furthermore,

the sampling memory 64 comprises an SRAM, and it sends the digital voltage signal Vb which has been temporarily stored for each frequency of the measurement signal Ia to the CPU 10 in accordance with a request from the CPU 10.

[0020] The voltage detection circuit 7 comprises: a differential amplifier 71, a bandpass filter (BPF) 72, an A/D converter 73 and a sampling memory (ring buffer) 74. The differential amplifier 71 detects the voltage Vp between the two surface electrodes Hp, Lp which are attached to the back of the hand H and the top of the foot L of the subject M. This voltage Vp constitutes a voltage drop brought about by the bioelectrical impedance of the body of the subject M between the surface electrode Hp and the surface electrode Lp. The bandpass filter 72 only allows the passage of the voltage signal component in the region of 1 kHz - 800 kHz from the voltage signal Vp which has been input, and this is then supplied to the A/D converter 73. The A/D converter 73 converts the analogue voltage signal Vp which has been input to a digital voltage signal Vp in accordance with a digital conversion instruction issued by the CPU 10, after which the digitized voltage signal Vp is stored in the sampling memory 74 as voltage data Vp for each sampling period and each frequency of the measurement signal Ia. The sampling memory 74 comprises an SRAM, and it sends the digital voltage signal which has been temporarily stored for each frequency of the measurement signal Ia to the CPU 10 in accordance with a request from the CPU 10. It should be noted that the CPU 10 issues digital conversion instructions at the same timing for the two A/D converters 63, 73.

[0021] The processing programs of the CPU 10 which are stored by the ROM 11 include various subprograms in addition to the main program, such as: an impedance measurement subprogram, an impedance locus generation

subprogram, a resistance value calculation subprogram, a fluid volume ratio calculation subprogram, an oedema diagnosis subprogram, a dehydration diagnosis subprogram and a display control subprogram. Furthermore, the upper limit value and the lower limit value for the fluid volume ratio between the intracellular fluid and the extracellular fluid in a healthy subject in a normal state which have been statistically processed in advance are preset and recorded in the ROM 11 as the standard fluid volume ratio.

[0022] The impedance measurement subprogram contains the procedure for successively reading out the current data and voltage data for each frequency which are temporarily stored in the sampling memories 64, 74 and for calculating the bioelectrical impedance Z(=Vp/Vb) in the subject M for each frequency. The impedance locus generation subprogram contains the processing procedure for obtaining the arc-shaped impedance locus D shown in Figure 3 using the least squares method for the calculation, in accordance with the bioelectrical impedance Z for each frequency which is obtained by execution of the impedance measurement subprogram. The resistance value calculation subprogram contains the procedure for obtaining the bioelectrical impedances R0, R∞ (comprising only the resistance component) at a frequency of 0 and infinite frequency in the body of the subject M from the arc-shaped impedance locus D obtained by execution of the impedance locus generation subprogram, in order to calculate the intracellular fluid resistance and extracellular fluid resistance in the body of the subject M from the bioelectrical impedances R0, R∞ at a frequency of 0 and infinite frequency which were obtained. Furthermore, the fluid volume ratio calculation subprogram contains the procedure for calculating the fluid volume ratio between the intracellular fluid and the extracellular fluid in the body of the subject M, on the basis of the

intracellular fluid resistance and extracellular fluid resistance which were calculated by execution of the resistance value calculation subprogram. In this case, the resistance ratio between the intracellular fluid resistance and extracellular fluid resistance may be treated as the fluid volume ratio between the intracellular fluid and the extracellular fluid.

[0023] The oedema diagnosis subprogram contains the procedure for determining (diagnosing) whether or not the subject M is suffering from oedema by comparing the fluid volume ratio between the intracellular fluid and the extracellular fluid of the subject which was calculated by execution of the fluid volume ratio calculation subprogram, and the standard fluid volume ratio (upper limit value) which is preset and recorded. The dehydration diagnosis subprogram contains the procedure for determining whether or not the subject is suffering from dehydration by comparing the fluid volume ratio between the intracellular fluid and the extracellular fluid of the subject which was calculated by execution of the fluid volume ratio calculation subprogram, and the standard fluid volume ratio (lower limit value) which is preset and recorded. Furthermore, the display control subprogram is used to provide message text which displays the procedure and determination results together in order to display on the display device 9 the determination (diagnosis) results from the oedema diagnosis subprogram or the dehydration diagnosis subprogram (e.g. "the subject is suffering from oedema", "the subject is suffering from dehydration", "the body fluids are normal", etc.).

[0024] The CPU 10 controls the various parts of the device by sequentially executing the various processing programs stored in the ROM 11 using the RAM 12, and determines if there is an abnormality (oedema or dehydration) in the distribution of water in the body of the subject M.

[0025] The operation of this example will be described next. First of all, before the measurement, the two surface electrodes Hc, Hp are attached to the back of the hand H of the subject, and the two surface electrodes Lp, Lc are attached to the top of the foot L on the same side of the subject with a conductive cream in between (at this point the surface electrodes Hc, Lc are attached at positions which are further from the centre of the body than the surface electrodes Hp, Lp, as shown in Figure 2). After this, the operator (or the subject him or herself) operates the mode setting switch 8b of the device 4A for diagnosing abnormalities in body fluids in order to set the oedema diagnosis mode, and when the start/end switch 8a is then pushed, the CPU 10 starts the operation in accordance with the processing flow shown in Figure 4. First of all, in step SP1, the CPU 10 issues a signal generation instruction signal SG to the measurement signal generator 52 of the signal output circuit 5. Driving of the measurement signal generator 52 starts when the signal generation instruction signal SG is received from the CPU 10, and the measurement signal generator 52 generates the measurement signal (current) Ia which is scanned over the range of 1 kHz - 400 kHz at intervals of 15 kHz, for example, throughout the whole measurement period and at a prescribed measurement period, and the signal is input to the output buffer 53. The output buffer 53 sends the input measurement signal Ia to the surface electrode Hc as the multi-frequency probe current Ib while maintaining the signal at a constant current (500 - 800 μa, for example). By means of this, the constant current probe current Ib flows from the surface electrode Hc into the body of the subject M.

[0026] When the multi-frequency probe current Ib is supplied to the body of the subject M, the I/V converter 6 of the current detection circuit 6 detects

the probe current Ib between the two surface electrodes Hc, Lc which are attached to the back of the right hand H and the top of the right foot L of the subject M with conductive cream in between, converts the current to the voltage signal Vb, and supplies the converted voltage signal Vb to the bandpass filter 62. The bandpass filter 62 only allows the passage of the voltage signal component in the region of 1 kHz – 800 kHz from the voltage signal Vb which has been input, and this is then supplied to the A/D converter 63. The A/D converter 63 converts the input analogue voltage signal Vb to a digital voltage signal Vb which is stored in the sampling memory 64 as current data Vb for each sampling period and each frequency of the measurement signal Ia. The sampling memory 64 sends the digital voltage signal Vb which has been stored to the CPU 10 in accordance with a request from the CPU 10.

[0027] Meanwhile, the differential amplifier 71 of the voltage detection circuit 7 detects the voltage Vp between the two surface electrodes Hp, Lp which are attached to the back of the right hand H and the top of the right foot L of the subject M with conductive cream in between. The bandpass filter 72 only allows the passage of the voltage signal component in the region of 1 kHz – 800 kHz from the voltage signal Vp which has been input, and this is then supplied to the A/D converter p3. The A/D converter 73 converts the input analogue voltage signal Vp to a digital voltage signal Vp which is stored in the sampling memory 74 as voltage data Vp for each sampling period and each frequency of the measurement signal Ia. The sampling memory 74 sends the digital voltage signal which has been stored to the CPU 10 in accordance with a request from the CPU 10.

[0028] When the measurement has ended, then in step SP2 the CPU 10 uses the RAM 12 to sequentially execute the impedance measurement subprogram, the impedance locus generation subprogram, the resistance value calculation

subprogram and the fluid volume ratio calculation subprogram. That is to say, the CPU 10 first of all successively reads out the current data Vb and voltage data Vp for each frequency which has been temporarily stored in the sampling memories 64, 74 and averages the values thereof in order to calculate the bioelectrical impedance Z(=Vp/Vb) for each frequency. Next, curve fitting is carried out using the least squares method for the calculation (see Figure 5) on the basis of the bioelectrical impedance Z for each frequency which has been calculated, and the impedance locus is obtained. Then the bioelectrical impedance R0 at a frequency of 0 in the body of the subject M and the bioelectrical impedance R∞ at infinite frequency (corresponding to the X coordinate value at the point where the arc of the impedance locus D intersects the X axis) are calculated from the impedance locus obtained, and the intracellular fluid resistance and the extracellular fluid resistance are calculated from the calculation result. In addition, the CPU 10 calculates the fluid volume ratio between the intracellular fluid and the extracellular fluid on the basis of the intracellular fluid resistance and the extracellular fluid resistance which were calculated.

[0029] (a) Oedema diagnosis mode

Proceeding to step SP3, the CPU 10 then looks at the mode setting flag and determines whether the current setting mode is the oedema diagnosis mode or the dehydration diagnosis mode. At this point, the oedema diagnosis mode is set by the operator (or the subject him or herself), and therefore the CPU 10 proceeds to step SP4 and runs the oedema diagnosis subprogram. The CPU 10 determines whether or not the subject M is suffering from oedema in accordance with the oedema diagnosis subprogram by comparing the fluid volume ratio between the intracellular fluid and extracellular fluid in the body of the subject M which was calculated in step SP2, and the standard fluid volume ratio (upper

limit value) which is preset and recorded. If it is determined in this determination that the fluid volume ratio between the intracellular fluid and extracellular fluid in the body of the subject M exceeds the standard fluid volume ratio (upper limit value), the CPU 10 proceeds to step SP5 in which the display control subprogram is executed and "the subject is suffering from oedema" is displayed on the display device 9 together with the fluid volume ratio etc. in the body of the subject M, as shown in Figure 5(a). On the other hand, if it is determined that the fluid volume ratio between the intracellular fluid and extracellular fluid in the body of the subject M does not exceed the standard fluid volume ratio (upper limit value), the CPU 10 proceeds to step SP6 in which the display control subprogram is executed and "the body fluid is normal" is displayed on the display device 9 together with the fluid volume ratio etc. in the body of the subject M, as shown in Figure 5(b). After this, the CPU 10 repeats the processing series (steps SP1 - SP5(6), step SP9) until the operator (or the subject him or herself) presses the start/end switch 8a.

[0030] (b) Dehydration diagnosis mode

When dehydration is to be diagnosed, the operator (or the subject him or herself) operates the mode setting switch of the device 4A for diagnosing abnormalities in body fluids, prior to the measurement, in order to set the dehydration diagnosis mode, and then when the start/end switch 8a is pressed, the CPU 10 executes the abovementioned measurement calculation processing (steps SP1 and SP2). Proceeding to step SP3, the CPU 10 then looks at the mode setting flag and determines whether the current setting mode is the oedema diagnosis mode or the dehydration diagnosis mode. This time the dehydration diagnosis mode has been selected, and therefore the CPU 10 proceeds to step SP7 and runs the dehydration diagnosis subprogram. The CPU 10 determines whether or not the subject M is suffering

from dehydration in accordance with the dehydration diagnosis subprogram by comparing the fluid volume ratio between the intracellular fluid and extracellular fluid in the body of the subject M which was calculated in step SP2, and the standard fluid volume ratio (lower limit value) which is preset and recorded. If it is determined in this determination that the fluid volume ratio between the intracellular fluid and extracellular fluid in the body of the subject M is less than the standard fluid volume ratio (lower limit value), the CPU 10 proceeds to step SP8 in which the display control subprogram is executed and "the subject is suffering from dehydration" is displayed on the display device 9 together with the fluid volume ratio between the intracellular fluid and extracellular fluid in the body of the subject M etc., as shown in Figure 6(a). On the other hand, if it is determined that the fluid volume ratio between the intracellular fluid and extracellular fluid in the body of the subject M is above the standard fluid volume ratio (lower limit value), the CPU 10 proceeds to step SP5 in which the display control subprogram is executed and "the body fluid is normal" is displayed on the display device 9 together with the fluid volume ratio etc. in the body of the subject M, as shown in Figure 6(b).

[0031] In this way, the configuration of this example is used to obtain the impedance locus using the least squares method for the calculation in accordance with the bioelectrical impedance Z(=Vp/Vb) measured for each frequency, and the bioelectrical impedance at a frequency of 0 and at an infinite frequency is calculated from the locus obtained, and therefore it is possible to avoid the effects of stray capacitance or exogenous noise in the high-frequency feed, and it is also possible to avoid direct feeding of direct current into the body. The bioelectrical impedance can therefore be measured more accurately.

[0032] Furthermore, the relationship in the balance between extracellular fluid and intracellular fluid (the proportions thereof) is(are) taken into account in determining abnormalities in body fluids, and therefore the result is consistent with the actual situation, and the reliability can be improved. Furthermore, an automatic diagnosis is carried out by the CPU 10, and therefore determination results can be quickly obtained through a simple operation, and the display device 9 provides a display on the screen indicating that: “the subject is suffering from oedema or dehydration” or “the body fluids of the subject are in a normal state”, and therefore it is very user-friendly. The invention can therefore be used as healthcare equipment to aid diagnosis in welfare institutions or in domestic settings, among others.

[0033] ◊ Second Exemplary Embodiment

Figure 7 is a block diagram showing the electrical configuration of a device 4B for diagnosing abnormalities in body fluids according to the second exemplary embodiment of the present invention. The main differences between the configuration of the second exemplary embodiment and that of the first exemplary embodiment described above lie in the fact that the start/end switch 8a and the mode setting switch 8b are lacking, and a keyboard 8c is added as a data input device instead, and in that the fluid volume ratio calculation subprogram is modified accordingly. The keyboard 8c comprises various function keys, including a measurement start/end key by means of which the operator (or the subject him or herself) instructs the start/end of measurement and a mode selection key by means of which the operator selects the oedema diagnosis mode or dehydration diagnosis mode, and also numeric keys for inputting body characteristics data such as the subject’s height, weight, age and sex; the operating data and the body characteristics data which are supplied through the keyboard 8c are converted to

code by a code generation circuit (not depicted) and then supplied to the CPU 10. The CPU 10 temporarily stores the various operating signals and body characteristics data which have been input in code in the data region of the RAM 12.

[0034] Furthermore, the fluid volume ratio calculation subprogram contains the procedure for calculating the fluid volume ratio between the intracellular fluid and the extracellular fluid in the body of the subject M, on the basis of the intracellular fluid resistance and extracellular fluid resistance which were calculated by execution of the resistance value calculation subprogram and the body characteristics data of the subject M input through the keyboard 8c. That is to say, the intracellular fluid resistance (extracellular fluid resistance) is obtained as the only variable in the first exemplary embodiment, whereas in the second exemplary embodiment the height, weight, age and sex are taken into account in addition to the intracellular fluid resistance (extracellular fluid resistance). It should be noted that the second exemplary embodiment is otherwise substantially the same as the first exemplary embodiment, and therefore structural components in Figure 7 which are the same as those in Figure 1 bear the same reference numbers and they will not be described again.

[0035] In this way, the configuration of the second exemplary embodiment takes account of the subject’s height, weight, age and sex and therefore makes it possible to obtain the fluid volume ratio even more accurately. This means that the reliability can be improved.

[0036] ◊ Third Exemplary Embodiment

The third exemplary embodiment will be described next. The configuration of the third exemplary embodiment is substantially the same as that of the second exemplary

embodiment described above with regard to the use of the keyboard 8c which serves as the means for inputting body characteristics data, but in the second exemplary embodiment the fluid volume ratio of the intracellular fluid and the extracellular fluid in the body of the subject M is calculated on the basis of the body characteristics data of the subject M which is input through the keyboard 8c, whereas the third exemplary embodiment differs a great deal from the second exemplary embodiment in that the optimum standard fluid volume ratio is selected on the basis of the body characteristics data of the subject M which is input through the keyboard 8c.

[0037] That is to say, the upper limit value and lower limit value of the fluid volume ratio between the intracellular fluid and the extracellular fluid in a healthy subject in a normal state are preset and recorded in the ROM 11 of this example as the standard fluid volume ratio for each body characteristics category consisting of height range, weight range, age range and sex, in correspondence to the input body characteristics data of the subject M supplied through the keyboard 8c. Furthermore, the oedema diagnosis subprogram contains the procedure for determining (diagnosing) whether or not the subject M is suffering from oedema by comparing the standard fluid volume ratio (upper limit value) which has been read out on the basis of the body characteristics data of the subject M supplied through the keyboard 8c, wherein the corresponding standard fluid volume ratio (upper limit value) is selectively read out from the ROM 11, and the fluid volume ratio between the intracellular fluid and the extracellular fluid of the subject M which was calculated by execution of the fluid volume ratio calculation subprogram. Likewise, the dehydration diagnosis subprogram contains the procedure for determining whether or not the subject is suffering from dehydration by comparing the standard fluid volume

ratio (lower limit value) which has been read out on the basis of the body characteristics data of the subject M supplied through the keyboard 8c, wherein the corresponding standard fluid volume ratio (lower limit value) is selectively read out from the ROM 11, and the fluid volume ratio between the intracellular fluid and the extracellular fluid of the subject M which was calculated by execution of the fluid volume ratio calculation subprogram.

[0038] In this way, the configuration of the third exemplary embodiment makes it possible to achieve substantially the same effect as in the second exemplary embodiment described above.

[0039] Exemplary embodiments of the present invention have been described above in detail in conjunction with the figures, but the specific configuration thereof is not limited to these exemplary embodiments, and the present invention also includes various design modifications within the scope of the invention. For example, the frequency range of the measurement signal (current) Ia is not limited to 1 kHz – 400 kHz. Likewise, any number of frequencies is possible, provided that there are multiple frequencies. Furthermore, it is equally feasible to calculate the bioelectrical admittance rather than the bioelectrical impedance, and the admittance locus may be calculated accordingly instead of the impedance locus.

[0040] Furthermore, in the exemplary embodiments described above, the bioelectrical impedance at a frequency of 0 and at an infinite frequency were obtained by means of curve fitting using the least squares method, but this is not limiting, and if stray capacitance and exogenous noise can be avoided by other means, then measurement signals may be generated for two frequencies, for example (low frequency of no more than 5 kHz and high frequency of at least 200 kHz)

which are fed into the subject, and the bioelectrical impedance at low frequency in the subject's body may be taken as the bioelectrical impedance at a frequency of 0, while the bioelectrical impedance at high frequency in the subject's body may be taken as the bioelectrical impedance at an infinite frequency. Furthermore, a description has been given in the exemplary embodiments above of a case in which the intracellular fluid resistance and extracellular fluid resistance in the subject's body are calculated, but this is not limiting, and the intracellular fluid resistance and extracellular fluid resistance may be obtained directly. Furthermore, the extracellular fluid resistance (or intracellular fluid resistance) and the total resistance may equally be obtained.

[0041] Furthermore, the keyboard 8c may equally be provided with a key for setting the total measurement time or measurement frequency etc., or for changing these settings, depending on the aim of the measurement. Furthermore, when the display device 9 displays a screen indicating that: "The patient is suffering from oedema (dehydration)", the state of progression of the oedema (dehydration) can be judged by providing a display on the screen indicating that: "The patient is suffering from slight oedema (dehydration)" or "The patient is suffering from serious oedema (dehydration)", etc., according to the degree of oedema (dehydration), and therefore the device can be made even more user-friendly. Furthermore, a description has been given in the exemplary embodiments above of a case in which the subject's height, weight, age and sex etc. are used as the body characteristics criteria, but sex and age etc. may be omitted, as required. Furthermore, a printer may also be added as an output device. Furthermore, in the exemplary embodiments described above, there are four surface electrodes Hp, Hc, Lp, Lc, and two of the surface electrodes Hc, Hp are attached to the back of the right hand H of the subject M, while the other two

surface electrodes Lp, Lc are attached to the back of the right foot L of the subject M, but this is not limiting, and the four surface electrodes may all be attached to the leg, as shown in Figure 8, for example.

[0042]

[Advantages of the Invention] As described above, the device for diagnosing abnormalities in body fluids according to the present invention is used to obtain the impedance locus using the least squares method for the calculation in accordance with the bioelectrical impedance Z(=Vp/Vb) measured for each frequency, and the bioelectrical impedance at a frequency of 0 and at an infinite frequency is calculated from the locus obtained, and therefore it is possible to avoid the effects of stray capacitance or exogenous noise in the high-frequency feed, and it is also possible to avoid direct feeding of direct current into the body. The bioelectrical impedance can therefore be measured more accurately. Furthermore, the relationship in the balance between extracellular fluid and intracellular fluid (the proportions thereof) is(are) taken into account in determining abnormalities in body fluids, and therefore the result is consistent with the actual situation, and the reliability can be improved. Furthermore, a computer is used as an automatic diagnostic device, and therefore determination results can be quickly obtained through a simple operation; in addition, the display device 9 provides a display on a screen indicating that: "the subject is suffering from oedema or dehydration" or "the body fluids of the subject are in a normal state", and therefore it is very user-friendly. The invention can therefore be used as healthcare equipment to aid diagnosis in welfare institutions or in domestic settings, among others.

[Brief Description of the Figures]

[Figure 1] is a block diagram showing the electrical configuration of the device for diagnosing

abnormalities in body fluids according to the first exemplary embodiment of the present invention;

[Figure 2] is a schematic showing the above diagnostic device in use;

[Figure 3] illustrates the operation of the above diagnostic device, and specifically it shows the impedance locus in the body;

[Figure 4] is a flowchart showing the processing procedure for operation of the above diagnostic device;

[Figure 5] shows an example of the display which is part of the above diagnostic device;

[Figure 6] shows an example of the display which is part of the above diagnostic device;

[Figure 7] is a block diagram showing the electrical configuration of a device for diagnosing abnormalities in body fluids according to the second exemplary embodiment of the present invention;

[Figure 8] is a schematic showing the diagnostic device of the first, second and third exemplary embodiments in a different state of use;

[Figure 9] illustrates conventional technology, showing a state in which low-frequency current and high-frequency current flow through cell tissue in the body; and

[Figure 10] illustrates conventional technology, where (a) is a simplified electrical equivalent circuit diagram of cells in body tissue, and (b) is a more realistic electrical equivalent circuit diagram.

[Key to Symbols]

1 cell

2 cell membrane

3 extracellular fluid

4A, 4B device for diagnosing abnormalities in body fluid

5 signal output circuit (structural component of bioelectrical impedance measurement means)

52 measurement signal generator (structural component of signal output circuit)

6 current detection circuit (structural component of bioelectrical impedance measurement means)

64 sampling memory (structural component of current detection circuit)

7 voltage detection circuit (structural component of bioelectrical impedance measurement means)

74 sampling memory (structural component of current detection circuit)

8c keyboard

9 display device

10 CPU (structural component of bioelectrical impedance measurement means; resistance value calculation means, fluid volume ratio calculation means, body fluid abnormality determination means, display control means)

11 ROM (memory means)

12 RAM (memory means)

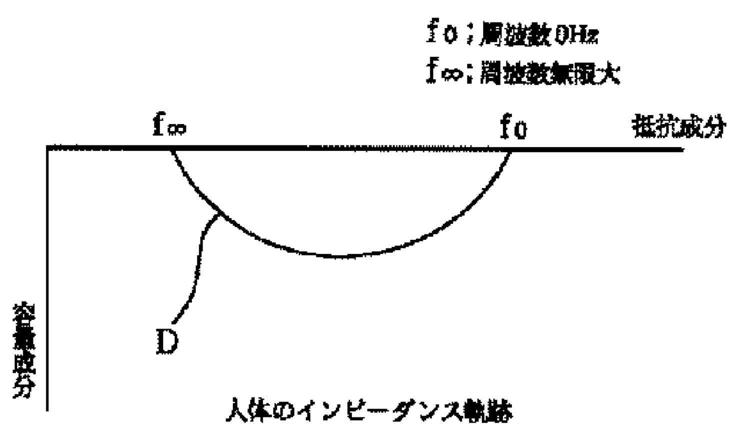
Ia measurement signal

Ib multi-frequency probe current

Vp detected voltage between hands and feet of subject

M subject

【図3】



[Figure 3]

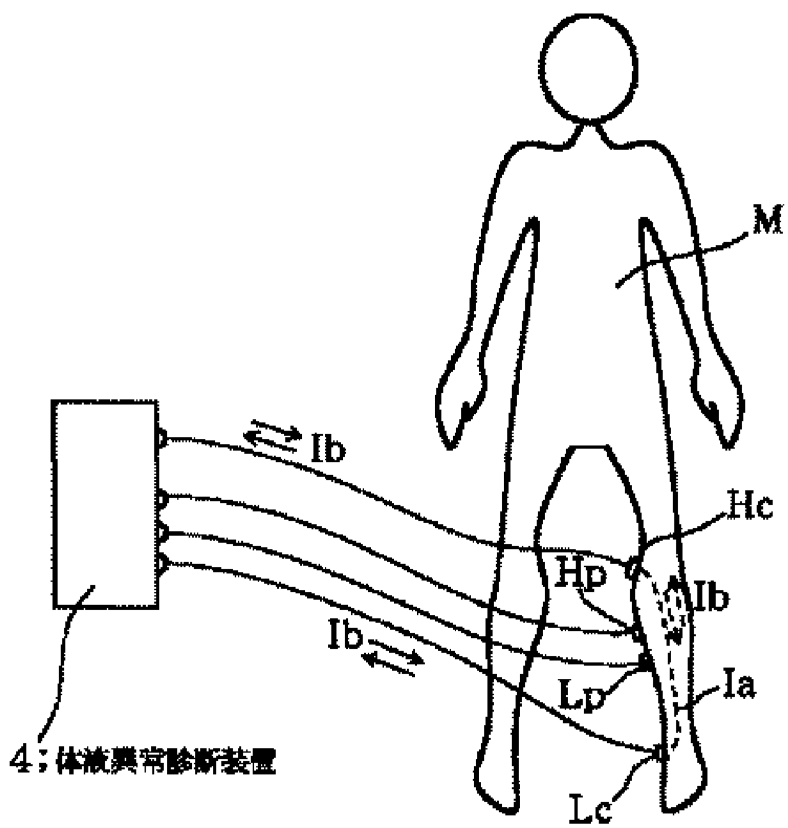
f0 frequency 0 Hz

f∞ infinite frequency

→ resistance component

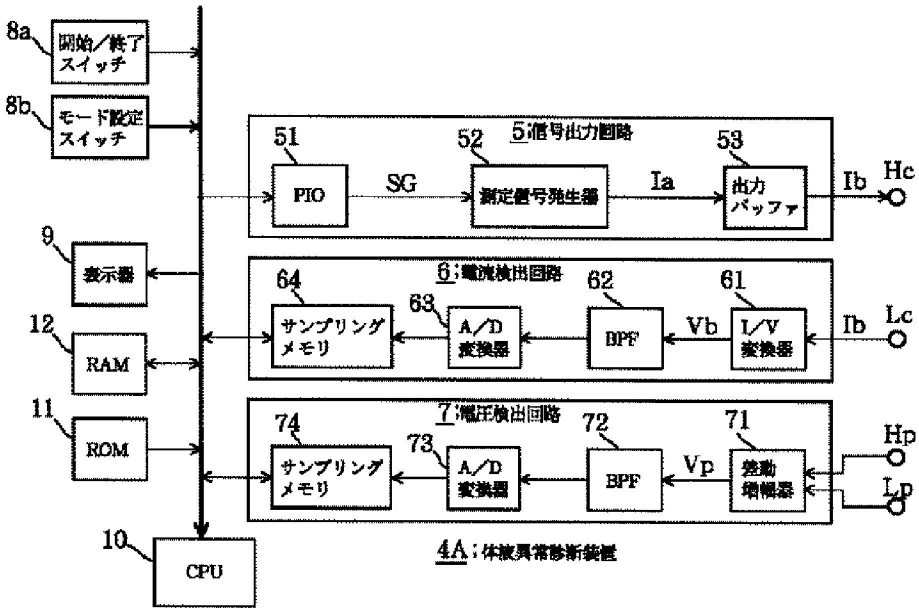
↓ capacitance component
body impedance locus

【図8】



[Figure 8]
4 device for diagnosing abnormalities in body fluid

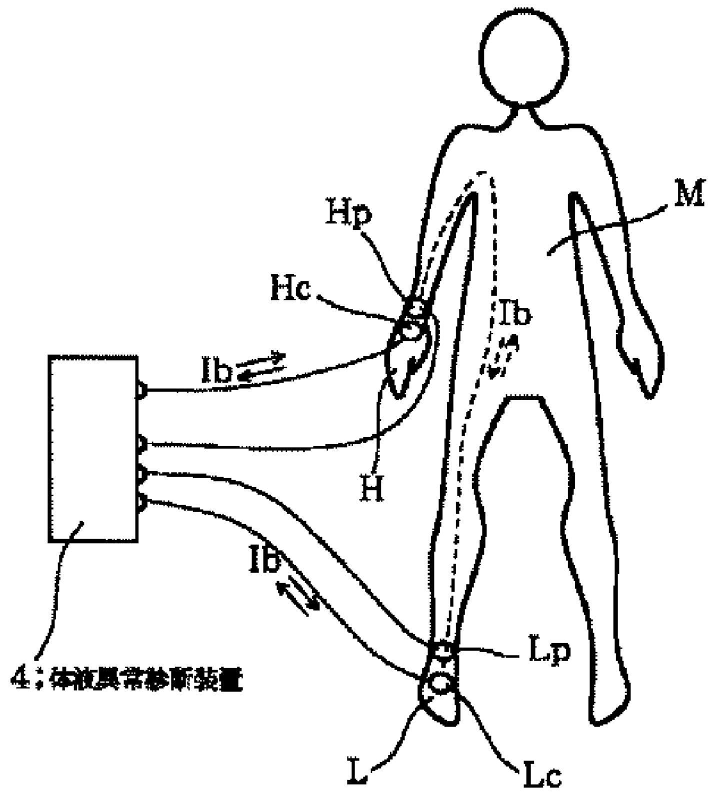
【図１】



[Figure 1]

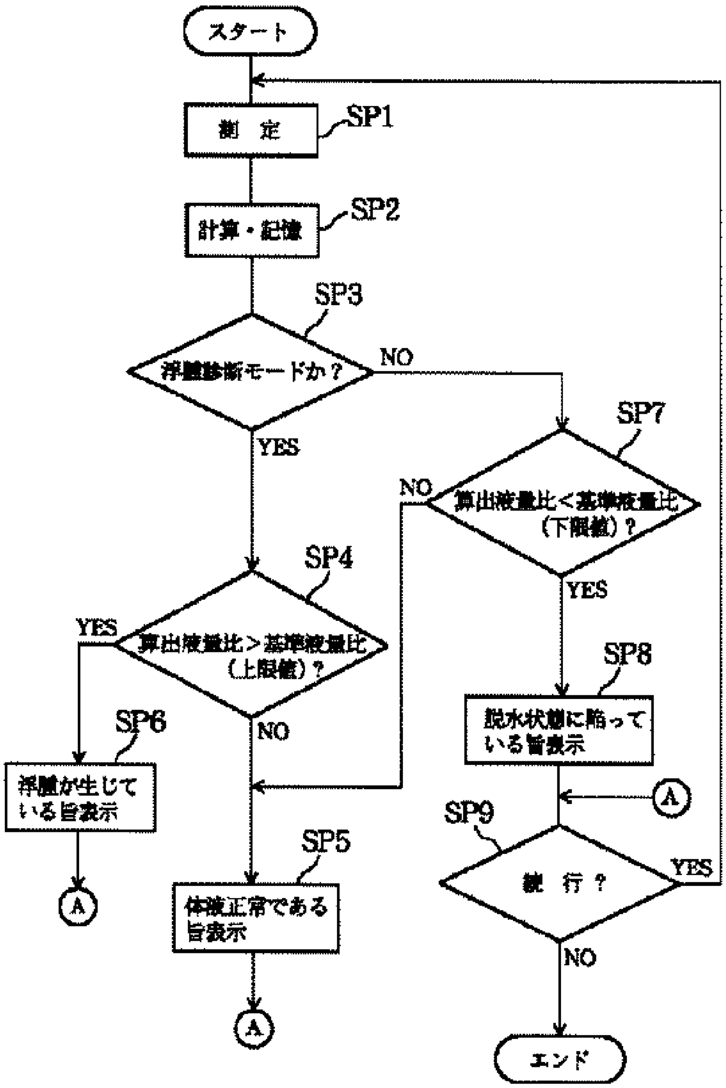
8a start/end switch
8b mode setting switch
9 display device
5 signal output circuit
52 measurement signal generator
53 output buffer
6 current detection circuit
64 sampling memory
63 A/D converter
61 I/V converter
7 voltage detection circuit
74 sampling memory
73 A/D converter
71 differential amplifier
4A device for diagnosing abnormalities in body fluids

【図2】



[Figure 2]
4 device for diagnosing abnormalities in body fluid

【図4】



[Figure 4]

START

SP1 measurement

SP2 calculation/storage

SP3 oedema diagnosis mode?

SP4 calculated fluid volume ratio > standard fluid volume ratio (upper limit value)?

SP5 display indicating that body fluid is normal

SP6 display indicating that subject is suffering from oedema

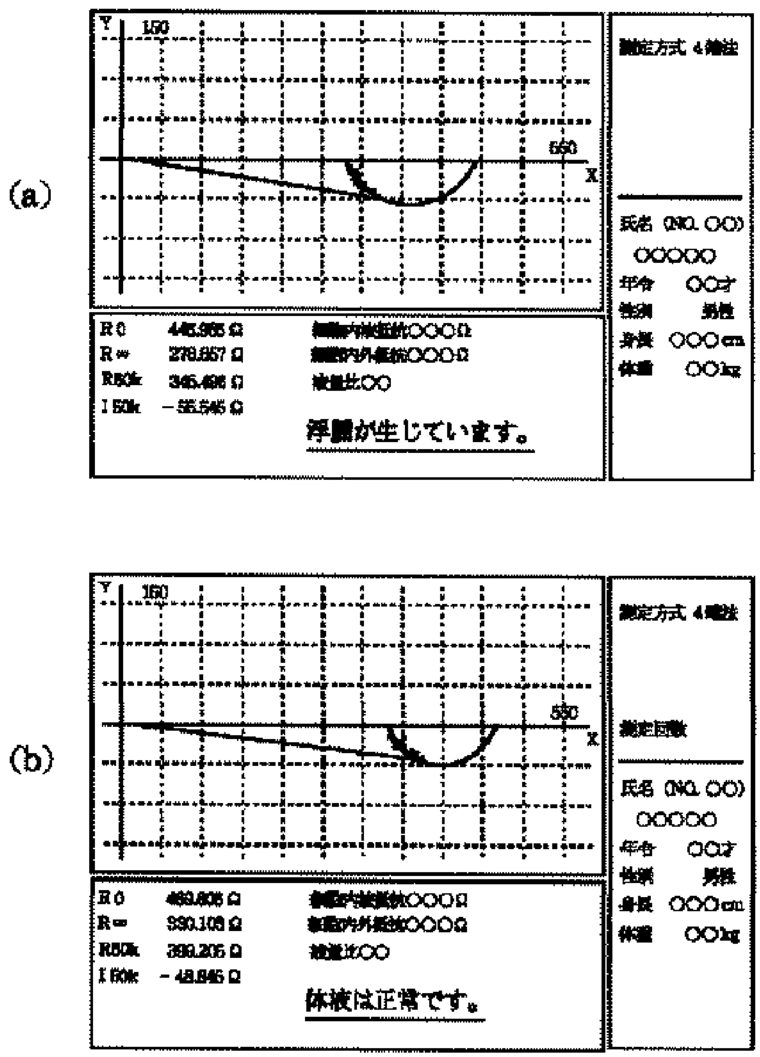
SP7 calculated fluid volume ratio < standard fluid volume ratio (lower limit value)?

SP8 display indicating that subject is suffering from dehydration

SP9 continue?

END

【図5】



[Figure 5]

(a)

Measurement method: 4 terminals

Name

Age __ years

Sex male

Height

Weight

Intracellular fluid resistance

Intracellular/extracellular fluid resistance

fluid volume ratio

The subject is suffering from oedema

(b)

Measurement method: 4 terminals

Number of measurements

Name

Age __ years

Sex male

Height

Weight

Intracellular fluid resistance

Intracellular/extracellular fluid resistance

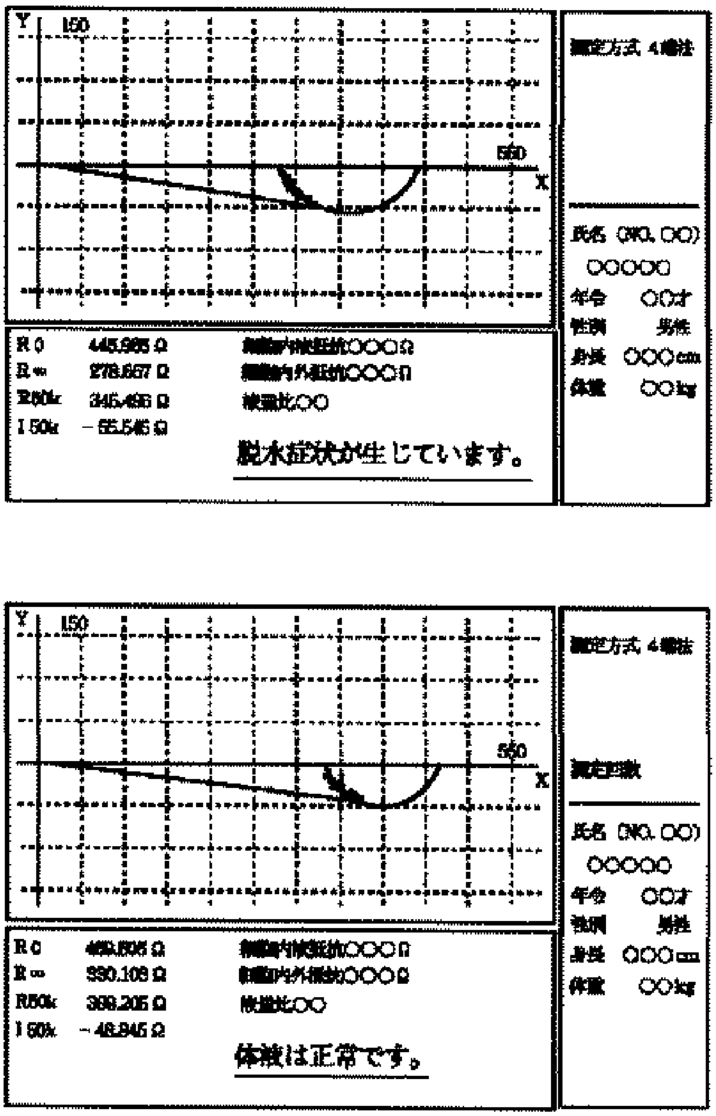
fluid volume ratio

Body fluids are normal

【図6】

(a)

(b)



[Figure 6]

(a)

Measurement method: 4 terminals

Name

Age __ years

Sex male

Height

Weight

Intracellular fluid resistance

Intracellular/extracellular fluid resistance

fluid volume ratio

The subject is suffering from dehydration

(b)

Measurement method: 4 terminals

Number of measurements

Name

Age __ years

Sex male

Height

Weight

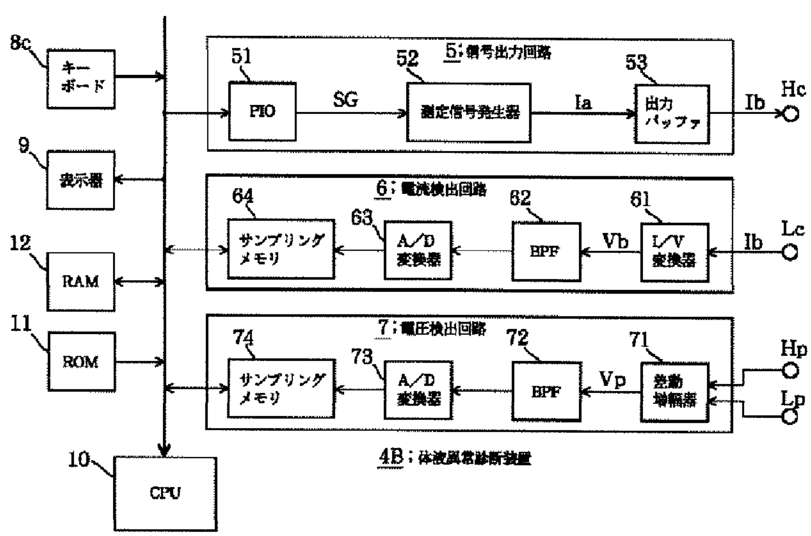
Intracellular fluid resistance

Intracellular/extracellular fluid resistance

fluid volume ratio

Body fluids are normal

【図7】



[Figure 7]

8c keyboard

9 display device

5 signal output circuit

52 measurement signal generator

53 output buffer

6 current detection circuit

64 sampling memory

63 A/D converter

61 I/V converter

7 voltage detection circuit

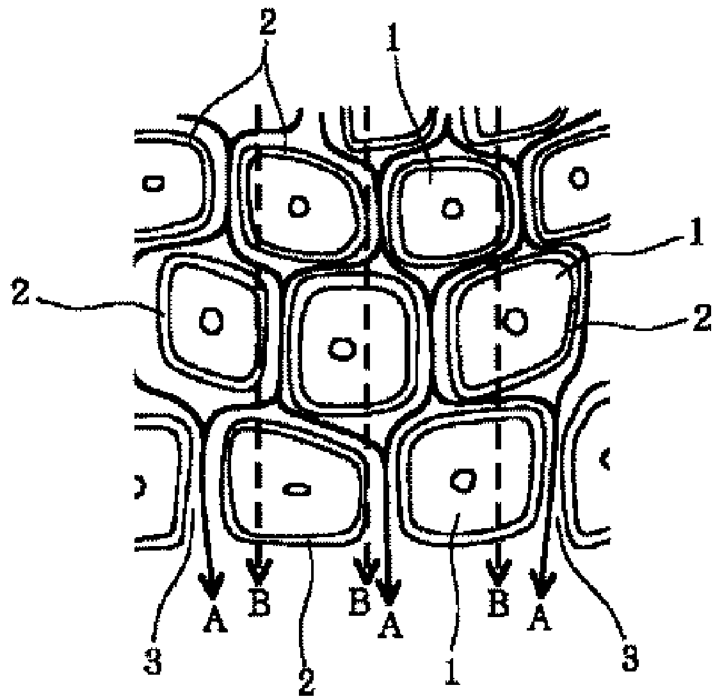
74 sampling memory

73 A/D converter

71 differential amplifier

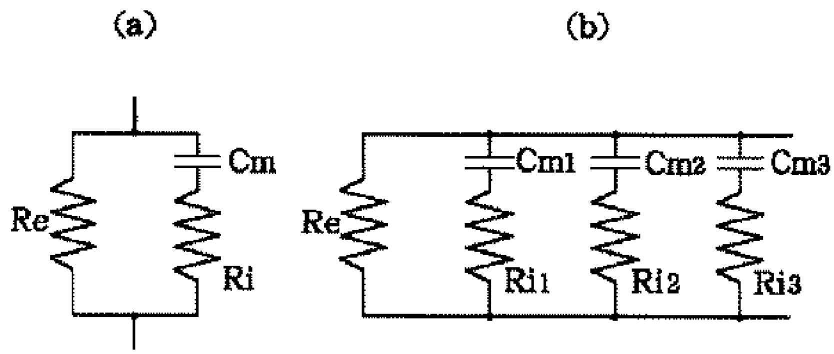
4B device for diagnosing abnormalities in body fluids

【図9】



[Figure 9]

【図10】



[Figure 10]